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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,128	03/12/2004	Eishun Tsuchida	0001606/2215USU	7075

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EXAMINER

FEDOWITZ, MATTHEW L

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/799,128

Applicant(s)

TSUCHIDA ET AL.

Examiner

Matthew L. Fedowitz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/24/2004</u> . | 6) <input type="checkbox"/> Other: ____  |

### DETAILED ACTION

Claims 1-8 are pending in this action.

#### *Claim Rejections - 35 USC § 112*

A. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification, while being enabling for the claimed compound of general formula (A), does not reasonably provide enablement where  $R_2$  is every residual group after the removal of an amino group and a carboxyl group from an  $\alpha$ -amino acid whether known or modified. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention without undue experimentation.

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the factual considerations. In re Wands, 8 USPQ2d 1400 (CAFC).

There are many factors to be considered when determining whether there is sufficient evidence

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to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include but are not limited to:

1. The breadth of the claims;
2. The nature of the invention;
3. The state of the prior art;
4. The level of one of ordinary skill;
5. The level of predictability in the art;
6. The amount of direction provided by the inventor;
7. The existence of working examples; and
8. The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

#### *Wands Analysis*

##### 1. The Breadth of the Claims.

The breadth of the instant claims are seen to encompass the compound of claim 1 and those compounds in claims 2-8 depending therefrom where  $R_2$  is a every residual group remaining after the removal of an amino group and a carboxyl group from and  $\alpha$ -amino acid of a known  $\alpha$ -amino acid or modified  $\alpha$ -amino acid.

##### 2. The Nature of the Invention.

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The nature of the invention is a porphyrin compound containing variables at position R1-R5, containing an ion from the transition metals of periods 4 and 5 that can be in the form of an albumin inclusion compound and artificial oxygen carrier.

### 3. The State of the Prior Art.

The applicant has submitted several patents and non-patent literature in both English and Japanese in order to demonstrate the state of the prior art on July 30, 2001. A close reading of the prior art submitted by the applicant as well as an independent search of the prior art does not reveal any teachings where R<sub>2</sub> can be synthesized as every residual group after the removal of an amino group and a carboxyl group from an  $\alpha$ -amino acid whether known or modified.

### 4. The Level of Ordinary Skill

In this case, it is important to determine the level of skill in the art at the time at which the applicant claims priority, that being July 30, 2001. The level of skill is that of one with a doctoral understanding of chemical synthesis.

### 5. The Level of Predictability in the Art

The chemical synthesis of porphyrin compounds is a highly unpredictable art. Moreover, synthesis in attaching every known or modified  $\alpha$ -amino acid, having the amine or carboxyl group removed, adds a level of uncertainty and unpredictability that the applicant has not demonstrated in the disclosure.

6. The Amount of Direction Provided by the Inventor

The applicant has not demonstrated sufficient guidance provided in the form of synthesis directions or adequate representations. Because the applicant has only submitted a limited number of examples to demonstrate the compounds claimed, the examples do not provide direction to the broad range of compounds claimed.

7. The Existence of Working Examples

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 27 USPQ2d 1510 (CAFC). The disclosure does not demonstrate sufficient evidence to support the applicant's claim the compound of claim 1 and the variations thereof in claims 2-8. There are not sufficient representations in the disclosure or data from references of the prior art to provide a nexus between those examples the ability to synthesize the compounds claimed.

8. The Quantity of Experimentation Needed to Make or Use the Invention Based on the Content of the Disclosure

In order to claim the compound of claim 1 and the variations thereof in dependent claims 2-8, it would be necessary to show that a vast range of different compounds based on claim 1 were able to be synthesized. Furthermore, direction, in the form of adequate representations, must be shown to demonstrate how these compounds were synthesized. The references

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submitted do not demonstrate this. Therefore, one of ordinary skill in the art would require a significant amount of experimentation in order to synthesize all of the claimed compounds.

B. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 defines  $R^1$  and  $R^3$  as a peptide having 1-6  $\alpha$ -amino acids and having a hydroxyl group (see specification p. 8 lines 24-25 and lines 12-15) and  $R^2$  is defined as a residual group after the removal of an amino group and a carboxyl group from an  $\alpha$ -amino acid. Further, to determine what residual groups  $R^2$  refers, the specification teaches that  $R^2$  denotes a  $-(R)CH$ -group in an  $\alpha$ -amino acid;  $H_2N(R)CHCOOH$  (for example, glycine ( $R=H$ ), alanine ( $R=-CH_3$ ), valine ( $R=-CH(CH_3)_2$ ), leucine ( $R=-CH_2CH(CH_3)_2$ ), and isoleucine ( $R=-CH(CH_3)C_2H_5$ ), that is a residual group after removal of an amino group and a carboxyl group from an  $\alpha$ -amino acid (see specification p. 9 lines 1-6).

$R^1$ - $R^3$  are indefinite because the " $\alpha$ " in  $\alpha$ -amino acid refers to the first carbon in the amino acid that is attached to the amino and carboxyl group (see Matthews *et al.* p. 129). By claiming  $\alpha$ -amino acids the applicant does not claim a specific class of amino acids but rather claims amino acids that contain an  $\alpha$ -amino acid. Currently, there are 20 known  $\alpha$ -amino acids, however, there are many modified  $\alpha$ -amino acids such as *o*-Phosphoserine and  $\gamma$ -

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Carboxyglutamic acid that are in existence (see Matthews *et al.* pp. 137-138) as well as an indefinite number of others. These modified amino acids vastly broaden the scope of  $\alpha$ -amino acids claimed to the extent where any removal of an amino group and a carboxyl group from and  $\alpha$ -amino acid could be included within the claim thereby rendering it indefinite.

Moreover, even though the applicant provides examples of amino acids where  $R^2$  represents glycine, alanine, valine, leucine and isoleucine (see Specification p. 9 lines 2-4), these examples do not delineate with specificity all of the amino acids that the applicant has claimed because it only lists a few examples from a larger grouping of amino acids that contain an  $\alpha$ -carbon.

In addition, the applicant has claimed the compound of claim 1 where  $R_1$  and  $R_3$  can be defined as containing a peptide with 1 amino acid. This claim is indefinite because peptides, by definition, contain more than one amino acid. In claiming a peptide with 1  $\alpha$ -amino acid the applicant has used a term that is repugnant to the usual meaning of the term (see MPEP 608.01(o)).

Claims 2-8 are also indefinite as depending from an indefinite base claim. Ex parte Cordova, 10 USPQ2d 1948, 1952.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew L. Fedowitz whose telephone number is (571) 272-3105 and can be reached between 9am-5:30pm (EST) M-F.



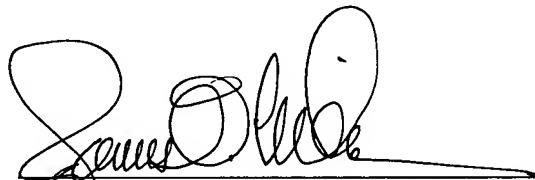
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Matthew L. Fedowitz, Pharm.D., J.D.  
November 9, 2004



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James O. Wilson  
Supervisory Patent Examiner  
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